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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/399,492 09/20/99 BAZAN

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HM12/0326

EXAMINER

CHERNYSHEV, D

ART UNIT

PAPER NUMBER

1646

DATE MAILED:

03/26/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/399,492

Applicant(s)

BAZAN, J. FERNANDO

Examiner

Olga N. Chernyshev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 8 and 11-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9 and 10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4, 6, 10
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Claims 1-20 are pending in the instant application.

Applicant's election with traverse of Group I, Claims 1-7 and 9-10 in Paper No. 12 is acknowledged. The traversal is on the ground(s) that a search for novelty of the polynucleotides encoding an IL-B50 polypeptide of Group I would eventually yield information regarding other groups and therefore examination of Groups I-V together would not be a serious burden on the Examiner. This is not found persuasive because an application may properly be required to be restricted to one of two or more claimed inventions if they are able to support separate patents and they are either independent (MPEP § 806.04 - § 806.04 (j)) or distinct (MPEP § 806.05 - § 806.05 (i)). The Examiner has shown that the Groups are independent or distinct for the reasons in the previous Office action (see Paper #11). Furthermore, MPEP § 803 provides that the separate classification (i.e., class and subclass) of distinct inventions is sufficient to establish a *prima facie* case that the search and examination of the plural inventions would impose a serious burden upon the Examiner; such separate classification was set forth in the Office action mailed 13 December, 2000 (Paper #11). Applicant has offered no evidence to rebut this showing. Therefore, a *prima facie* case for a serious search burden was presented in Paper #11 and Applicant has offered no evidence to rebut this showing.

The requirement is still deemed proper and is therefore made FINAL.

Claims 8, 11-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in Paper No. 12.

Claims 1-7 and 9-10 are under examination in the instant office action.

Specification

2. The instant application contains separate Sequence Listing in the Specification and Sequence listing as a part of Specification. It is suggested that pages 10-11 are deleted from the Specification in order not to duplicate information.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1-7 and 9-10 are rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility. The instant application has provided a description of an isolated polynucleotide encoding a polypeptide and the polypeptide encoded thereby. The instant application does not disclose the biological role of this protein or its significance.

It is clear from the instant application that the polypeptide described therein is what is termed an "orphan protein" in the art. The DNA of the instant application has been isolated because of its similarity to a known DNA. There is little doubt that, after complete

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characterization, this DNA and encoded protein may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediate obvious or fully disclosed "real world" utility. The court held that:

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion".

The instant claims are drawn to a DNA and the protein encoded thereby of as yet undetermined function or biological significance. It is clear from the instant application that the protein described thereby is similar to Interleukin-7: "The present invention is based, in part, upon the discovery of a new cytokine sequence exhibiting significant sequence and structural similarity to IL-7" (page 4, lines 20-22 of the specification). It has been suggested that "The full length cytokines, and fragments, or antagonists will be useful in physiological modulation of cells expressing a receptor. It is likely that IL-B50 has either stimulatory or inhibitory effects on

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hematopoietic cells, including, e.g., lymphoid cells, such as T-cells, B-cells, natural killer (NK) cells, macrophages, dendritic cells, hematopoietic progenitors, etc.” (page 9, lines 7-13) (emphasis added by the Examiner).

In the absence of knowledge of the biological significance of this specific DNA and encoded protein, there is no immediately obvious patentable use for the polynucleotide or the encoded protein. First, the similarity of the disclosed DNA to a DNA associated with IL-7, a member of a family of interleukins, which is characterized by a wide and diverse range of activities (see page 2, lines 20-21 - of the specification), does not make the instant DNA or encoded protein obviously useful. Second, the specification alleges that the sequence similarity of IL-B50 to IL-7 is significant. However, according to the information on sequence alignments (see a copy of the printout provided), the sequence similarity between IL-B50 and IL-7 is only 28.1%. Based on this limited degree of similarity, one of ordinary skill in the art would not reasonably conclude that the disclosed protein possesses any or all of the biological activities of IL-7, especially in light of the specification's statement of “stimulatory or inhibitory effects” (see page 9).

To employ the DNA and the protein in the future methods of modulating physiology or development of a cell is not a real world ^{use} because it would eventually relate to a protein for which little biological function is known. As it is indicated in the specification of the instant application, it is not clear and can be only assumed at this time that IL-B50 will have an effect, either stimulatory or inhibitory on hematopoietic cells (see page 9 of the specification and earlier in this office action). In other words, to employ a DNA of the instant invention in any of the disclosed methods would clearly be using it as the object of further research which has been

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determined by the courts to be a utility which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for the encoded protein then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

4. Claims 1-7 and 9-10 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 2 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1, 2 are directed to proteins in their mature form. However, the instant specification fails to describe proteins, which are encompassed by these claims. In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicant has possession of and what Applicant is claiming. From the specification, it is clear that Applicant has possession of a

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nucleic acid molecule which encodes a protein which has the amino acid sequence of SEQ ID NO:2 or 4. The subject matter which is claimed is described above. First, a determination of the level of predictability in the art must be made in that whether the level of skill in the art leads to a predictability of structure; and/or whether teachings in the application or prior art lead to a predictability of structure. The recitation of the mature form of a polypeptide implies a process of natural processing of the protein within a cell. It is well known in the art that different cells process proteins differently, which eventually leads to variations in a protein structure. The specification only describes a protein having the amino acid sequence of SEQ ID NO:2 or 4 and fails to teach or describe any other protein which is a mature form of the claimed polypeptide. The specification indicates that the mature sequence comprises "the sequence from Table 1" (see page 4, lines 34-35), but the sequence of Table 1 is the full-length protein. Therefore, there is a lack of guidance or teaching regarding structure and function of "mature" form of claimed polypeptide.

Next in making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, each claimed species and genus must be evaluated to determine whether there is sufficient written description to inform a skilled artisan that applicant was in possession of the claimed invention at the time the application was filed. With this regard, the instant application fails to provide a written description of the species or the genus which are encompassed by the instant claims except for the protein of SEQ ID NO:2 or 4. The specification does not provide a complete structure of those polypeptides which are considered to be in the form of mature polypeptide. The claims also fail to recite other relevant identifying characteristics (physical and/or chemical and/or functional characteristics coupled

with a known or disclosed correlation between function and structure) sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. The specification fails to provide a representative number of species for the claimed genus (those proteins which have identified structure of mature form of polypeptide) because the specification teaches only the embodiment of SEQ ID NO:2 and 4. Therefore, the claims are directed to subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

If Applicant intends a mature protein to have an amino acid sequence of AA. 34-116 of SEQ ID NO:2, then the claims should be directed to this protein, and not to "mature", for which the specification lacks an adequate written description.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is indefinite for recitation of "stringent hybridization conditions". Claim 9 is directed to a polynucleotide, which hybridizes under stringent conditions. However, the metes and bounds of "stringent hybridization conditions" cannot be determined from the claim. There

are a multitude of conditions that are used by the skilled artisan which could be considered, which range from low stringency to high stringency, all of which depend on a number of variables in the hybridization process. Without knowing which set of conditions are intended by the claim, one would not be able to determine the metes and bounds of the claim. Should Applicant include specific conditions for stringent hybridization from specification (possibly at page 7, lines 4-8) or claim 3, the rejection could be avoided.

Claim 9 recites the limitation "a polynucleotide". There is insufficient antecedent basis for this limitation in the claim. This ground of rejection could be avoided if recitation of "the polynucleotide" is used.

Conclusion

7. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-0294 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax

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center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D. *OC*
March 25, 2001

CHRISTINE J. SAOUD
PRIMARY EXAMINER
Christine J. Saoud